

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention**

[60Day-21-1100; Docket No. CDC-2021-0066]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT), which collects information from people testing for HIV in order to compare the performance characteristics of new point of care HIV tests for detection of early HIV infection and to identify behavioral and clinical predictors of early HIV infection.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0066 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension

of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Identification of Behavioral and Clinical Predictors of

Early HIV Infection (Project DETECT) - (OMB Control No. 0920-1100, Exp. 1/31/2022) - Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a three-year Extension for a data collection titled Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT).

CDC provides guidelines for HIV testing and diagnosis for the United States, as well as technical guidance for its grantees. The purpose of this project is to assess characteristics of HIV testing technologies to update these guidance documents to reflect the latest available testing technologies, their performance characteristics, and considerations regarding their use. Specifically, CDC will describe behavioral and clinical characteristics of persons with early infection to help HIV test providers (including CDC grantees) choose which HIV tests to use, and target tests appropriately to persons at different levels of risk. This information will be disseminated primarily through guidance documents and articles in peer-reviewed journals.

The primary study population will be persons at high risk for, or diagnosed with HIV infection, many of whom will be men who have sex with men (MSM), transgender women, minorities, and persons who inject drugs (PWIDs) because the majority of new HIV infections occur each year among these populations. The goals of the project are to: (1) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care, relative to each other and to currently used gold standard, non-point-of-care (POC) tests, and (2) identify behavioral and clinical predictors of early HIV infection.

Project DETECT will enroll 1,867 persons annually from two study sites (Seattle and Baltimore). The study will be conducted in two phases.

Phase 1: After a client consents to participate, he/she will be assigned a unique Participant ID, and will then undergo testing with up to seven new HIV tests under study. While awaiting test results, participants will undergo additional specimen collections and complete the Phase 1 Enrollment Survey.

Phase 2: All Phase 1 participants whose results on the seven tests under investigation are not in agreement with one another test (discordant), will be considered to have a potential early HIV infection. Nucleic amplification testing that detects viral nucleic acids will be conducted to confirm an HIV diagnosis and rule out false positives. Study investigators expect that each year, 50 participants with discordant test results will be invited to participate in serial follow-up

specimen collections to assess the time point at which all HIV test results resolve and become concordant positive (indicating enrollment during early infection) or concordant negative (indicating one or more false-positive test results in Phase 1).

The follow-up schedule will consist of up to nine visits scheduled at regular intervals over a 70-day period. At each follow-up visit, participants will be tested with the new HIV tests and additional oral fluid and blood specimens will also be collected for storage and use in future HIV test evaluations at CDC. Participants will be followed only to the point at which all their test results become concordant. At each time point, participants will be asked to complete the Phase 2 HIV Symptom and Care survey to collect information on symptoms associated with early HIV infection as well as access to HIV care and treatment since the last Phase 2 visit. When all tests become concordant (i.e., at the last Phase 2 visit) participants will complete the Phase 2 Behavioral Survey to identify any behavioral changes during follow-up. Of the 50 Phase 2 participants; it is estimated that no more than 26, annually, will have early HIV infection.

All data for the proposed information collection will be collected via an electronic Computer Assisted Self-Interview (CASI) survey. Participants will complete the surveys on an encrypted computer, with the exception of the Phase 2 Symptom and Care survey, which will be administered by a research assistant and then electronically entered into the CASI system.

Data to be collected via CASI include questions on sociodemographic characteristics, medical care, HIV testing, pre-exposure prophylaxis, antiretroviral treatment, sexually transmitted diseases (STD) history, symptoms of early HIV infection, substance use and sexual behavior.

Data from the surveys will be merged with HIV test results and relevant clinical data using the unique identification (ID) number. Data will be stored on a secure server managed by the awardee's Information Technology (IT) Services. The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total estimated annual burden hours for the proposed project are 1,594 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Persons eligible for study	Phase 1 Consent	2,334	1	15/60	584
Enrolled participants	Phase 1 Enrollment Survey	1,867	1	30/60	934
	Phase 2 Consent	50	1	15/60	13
	Phase 2 HIV Symptom and Care survey	50	9	5/60	38
	Phase 2 Behavioral Survey	50	1	30/60	25
Total					1,594

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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